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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,292	03/10/2004	Kunwar Shailubhai	122069-40308707	9377
909 7590 01/15/2009 PILLSBURY WINTHROP SHAW PITTMAN, LLP P.O. BOX 10500 MCLEAN, VA 22102				
EXAMINER GEMBEH, SHURLEY V				
ART UNIT 1618		PAPER NUMBER		
MAIL DATE 01/15/2009		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/796,292

Applicant(s)

SHAILUBHAI ET AL.

Examiner

SHIRLEY V. GEMBEH

Art Unit

1618

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-12, 21-22, 25-30, 33, 35-37 and 39-48 - is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-12, 21-22, 25-30, 33, 35-37 and 39-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The response filed on **9/22/08** has been entered.
2. Applicant's arguments filed on 9/22/08 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 11-12, 21-22, 25-30, 33, 35-37 and 39-48 are pending in this office action.
5. Claims 11-12, 21-22, 25-30, 35-37 and 46-48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Rice et al. (1973) and Mirabelli et al. (1989) in view of Badger et al. (US 5,602,166) and Dagger et al. (US 5,939,450) for the reasons made of record in Paper No. 20080320 and as follows.

Applicant argues that the unexpected results should overcome the 103 rejection.

In response, for unexpected results to be persuasive, the unexpected result must truly be unexpected. There should be comparison of the closest prior art with the claim invention and the result must be commensurate in scope with the claim invention.

So far, Applicant has not demonstrated the superiority of the claimed invention over the prior art of record. Applicant should note that Rice teaches that introductory of a methyl group at these positions increase the inhibitory activity five folds in human mammary cancer and suggested further substitutions. See page 731, left. col. under abstract, lines 4-8. Based on such a teaching one of ordinary skill in the art would have been motivated to explore other alkanes at that position, especially when combined with Badger, wherein the same compound as claimed is employed for the treatment of diseases related to brain astrocytes (i.e., brain tumor and CNS cancer), or related to epidermal keratinocytes (i.e., skin cancer or melanoma; see col. 2, lines 50-55; as it relates to instant claim 11). Therefore it would have been obvious to one of ordinary skill in the art to expand the core structure by substituting varying alkanes at position 8 for increasing potency in the treatment of cancers, such as mammary/ breast cancer, brain cancer, etc., as taught by both Rice and Badger of record.

In summary, Rice teaches homologs of the claimed compound, such as N,N-dimethyl-8,8-dipropyl-2-azaspiro[4,5]decane, for treatment of mammary cancers, wherein a change from H to methyl at position 8 gave a five fold increase in the inhibition of mammary cancer (see page 731, 1st col.). Therefore one of ordinary skill in the art would have been motivated to at the time the invention was made to modify the closest compound known in the art, as pointed out above, by modifying the hydrogen with alkanes and in so doing obtain additional compounds for treating cancer in view of the close structural similarity outlined above.

Applicant should note that Rice was used to show that the activity of the compounds of Rice is increased with the change in substituents. Therefore, the combination of references renders the claim invention obvious, in contrast to Applicants' assertions. Thus, the unexpected result as relied upon by Applicant is not persuasive. See discussion supra.

Careful consideration has been given, but is found not persuasive, especially as it relates to the claims merely requiring "a method of treating cancer..." . Therefore, the rejection is maintained for the reasons made of record.

6. Claims 11-12, 21-22, 25-30, 35-37 and 46-48 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent Application No. 10548794 for the reasons made of record in Paper No. 20080320.

Applicant's request that the Double Patenting rejection be held in abeyance until it is made permanent is noted but will be maintained in this Office Action and future Office Actions until withdrawn.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1618

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
1/6/09

/Robert C. Hayes/
Primary Examiner, Art Unit 1649

